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December 18, 2007

By E-Filing

The Honorable Joseph J. Farnan, Jr.
United States District Court
844 King Street
Wilmington, DE 19801

Re: Wyeth v. Impax, C.A. No. 06-222 (JJF)

Dear Judge Farnan:

Wyeth writes to bring to the Court's attention a new development relating to Wyeth's Motion To Strike The Expert Reports Of Impax's Patent Law Expert, Mark E. Nusbaum (the "Motion to Strike") (D.I. 275).

The Court made clear at the November 9, 2007 hearing that the only circumstances under which it might permit Mr. Nusbaum's proposed testimony were if Impax had "no other way to get that evidence in the record," such as through another expert witness. (D.I. 294, Tr. at 5). The Court explained that:

> Again, my view is that it's something you need in the trial record ***that isn't otherwise available to you by another witness***, particularly an expert witness that you couldn't establish any other way than by expert testimony, and ***whatever it is that Mr. Nusbaum is unique***, that he is the person that can present that for you and lay that issue out so that you have it in the record for any appeal that might be necessitated by an adverse ruling to you at trial.

(*Id.* at 5-6, emphasis added). The Court further noted that it did not need a patent law expert to advise it on matters of Patent Office procedure. (*Id.* at 2-3). As Wyeth pointed out in its response to Impax's supplemental brief (D.I. 313), Impax did not heed the Court's direction. And Impax's December 14, 2007 draft of its proposed witness list confirms that Impax continues not to heed the Court's direction. It describes Mr. Nusbaum's proposed testimony as follows:

> Mr. Nusbaum is expected to testify regarding issues related to Impax's counterclaim for inequitable conduct by Wyeth in withholding material prior-art references from the PTO during prosecution of the patents-in-suit. Specifically, ***he is expected to testify regarding PTO standards and practices regarding examination of patent applications in light of prior art, and the application of those standards to the Wyeth applications that matured into the patents-in-suit***.

(Ex. A at 4, emphasis added).

Thus, notwithstanding the Court's ruling, Impax continues to offer the same broad scope of testimony for Mr. Nusbaum. This is exactly the sort of testimony that this Court has repeatedly precluded. Wyeth's Motion to Strike should be granted.

Respectfully,

/s/ Karen Jacobs Louden
Karen Jacobs Louden

/cbh
cc: Peter T. Dalleo, Clerk (By hand)
Mary B. Matterer, Esq. (By email)
Daralyn Durie, Esq. (By email)
Basil J. Lewris, Esq. (By email)
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EXHIBIT A

WITNESSES IMPAX INTENDS TO CALL IN PERSON

Impax presently intends to call the witnesses identified below to testify in person at trial, or by deposition if those witnesses are unavailable. Impax reserves the right to call any witness identified on Wyeth's witness list.[1]

A. Fact Witnesses

Dr. Robin Enever	Wyeth Five Giralda Farms Madison, New Jersey 07940
Dr. Charles Hsiao	Impax Laboratories, Inc. 30831 Huntwood Avenue Hayward, California 94544
Deborah Sherman	Wyeth Five Giralda Farms Madison, New Jersey 07940
Ted Smolenski	Impax Laboratories, Inc. 30831 Huntwood Avenue Hayward, California 94544

B. Expert Witnesses

Dr. William S. Comanor	Economic Associates 4141 LaSalle Avenue Culver City, California 90232

Dr. Comanor is a Professor of Economics at the University of California, Santa Barbara and a Professor of Health Services at the School of Public Health at the University of California, Los Angeles. At UCLA, he founded the Research Program on Pharmaceutical Economics and Policy, where he is currently the Director. His writings on the economics of research and development in the pharmaceutical industry dates from the completion of his dissertation in 1963. He received his Ph.D. in economics from Harvard University in 1964. In 1965-66, he

[1] Impax has made its best efforts to provide herein the current addresses of current or former Wyeth employees. Those addresses are better known to Wyeth than Impax.

served as Special Economic Assistant to the Assistant Attorney General in charge of the Antitrust Division of the United States Department of Justice. Following that, he served as Assistant and Associate Professor of Economics at Harvard University and Stanford University. In 1975, he joined the faculty of the University of California. From 1978-80, he took a leave from his faculty position to serve as Director of the Bureau of Economics at the Federal Trade Commission in Washington, D.C., where he supervised a staff of over 200 employees, including more than 85 economists. His staff was responsible for providing economic support for all Commission activities as well as for carrying our economic research activities that dealt with competition issues. In April 2003, he was awarded the Distinguished Fellow Award by the Industrial Organization Society. That award is given annually in recognition of excellence in research, education, and professional leadership in the field of industrial organization. During his career, he has studied, lectured, written, and consulted extensively on issues dealing with the pharmaceutical industry.

Dr. Comanor may testify as to the absence of a nexus between the commercial success of Wyeth's Effexor® XR product and the invention claimed in Wyeth's United States Patent Nos. 6,274,171, 6,403,121, and 6,419,958 ("the Wyeth patents" or "the patents-in-suit"). Dr. Comanor is expected to testify about some of the factors that can affect the demand for pharmaceutical products like venlafaxine. More specifically, he is expected to testify that the commercial success of Effexor XR® is largely the result of Wyeth's marketing and promotional activities, along with the well-known and inherent benefits of the active ingredient, rather than Wyeth's extended-release formulation.

Dr. Arthur Kibbe

Wilkes University
Box 111
Wilkes-Barre, Pennsylvania 18766

Dr. Kibbe is a pharmaceutical formulations scientist with over 35 years of experience in the fields of biopharmaceutics, pharmacokinetics, and pharmaceutical excipients. He is currently

a Professor of Pharmaceutical Sciences at Wilkes University in Wilkes-Barre, Pennsylvania, and a consultant to the pharmaceutical industry. He received his Ph.D. in pharmacy and pharmaceutics from the University of Florida in 1973. In addition to his teaching career, he has worked with the pharmaceutical industry in various capacities. He has served as Senior Director of Professional and Scientific Affairs of the American Pharmaceutical Association, and has chaired the Pharmaceutical Advisory Commission of the U.S. Food and Drug Administration. In these capacities and others, he has worked with, consulted about, and evaluated extended-release formulations of various pharmaceutical products. He was editor-in-chief of the third edition of the internationally-recognized reference text, *Handbook of Pharmaceutical Excipients,* and has continued on the steering committee for all subsequent editions. He has trained professional pharmacists and pharmaceutical scientists, including over a dozen Ph.D.s currently working as formulators in the pharmaceutical industry.

Dr. Kibbe is expected to testify on the validity of the patents-in-suit. Specifically, he will testify that Wyeth's extended-release venlafaxine formulation was obvious in light of the prior art, and lacks the required written description of any formulation containing any ingredients other than those used in Effexor XR®. He is further expected to testify in rebuttal to Wyeth's experts regarding the meanings or indefiniteness of certain claim terms, if Wyeth's experts are permitted to offer testimony on the meanings of such terms. He is further expected to testify about the generic drug industry and the requirements for FDA approval, labeling, and marketing of a bioequivalent generic drug.

Mark Nusbaum

Nixon & Vanderhye, P.C.
11th Floor
901 North Glebe Road
Arlington, Virginia 22203-1808

Mr. Nusbaum is a patent attorney and a former examiner for the United States Patent and Trademark Office. He received a bachelor's degree in electrical engineering from the University of Maryland in 1969, after which he joined the PTO as an Examiner. He later received his J.D.

degree from American University in 1974. While at the PTO, he received the authority to grant or deny patents over his own signature in 1975, became a Senior Examiner in 1977, and was appointed a Supervisory Patent Examiner in 1980. In that latter position, he was responsible for training examiners, reviewing examiner work product, granting or denying patent applications, and assisting junior examiners in making patentability decisions. In 1983, he was appointed Examiner-in-Chief and a member of the Board of Patent Appeals and Interferences, the quasi-judicial appellate body that hears appeals from decisions of primary examiners adverse to patent applicants. Mr. Nusbaum's work on the Board required a detailed understanding of patent claims and how they should be construed, as well as an understanding and application of the pertinent statutes, precedents, rules, and other regulations regarding the examination of patent applications. While on the Board, he participated in approximately 500 to 750 appeals. In 1986, Mr. Nusbaum left the PTO to become a member of the Nixon & Vanderhye intellectual-property law firm, where he specializes in all phases of patent application preparation and prosecution and has served as an expert witness in PTO practice and patent law in patent-infringement suits.

Mr. Nusbaum is expected to testify regarding issues related to Impax's counterclaim for inequitable conduct by Wyeth in withholding material prior-art references from the PTO during prosecution of the patents-in-suit. Specifically, he is expected to testify regarding PTO standards and practices regarding examination of patent applications in light of prior art, and the application of those standards to the Wyeth applications that matured into the patents-in-suit.

Dr. Jon M. Riddle

Economic Associates
4141 LaSalle Avenue
Culver City, California 90232

Dr. Riddle is an Adjunct Assistant Professor at the School of Public Health at the University of California, Los Angeles. He received a Ph.D. in Economics from the University of California, Santa Barbara. Currently, he teaches microeconomic theory of the health sector and empirical methods for UCLA's Executive Master of Public Health (EMPH) program. He also

teaches economics and finance courses at both UCLA and the University of California, Santa Barbara.

Dr. Riddle may testify as to the absence of a nexus between the commercial success of Wyeth's Effexor® XR product and the invention claimed in Wyeth's United States Patent Nos. 6,274,171, 6,403,121, and 6,419,958 ("the Wyeth patents" or "the patents-in-suit"). Dr. Comanor is expected to testify about some of the factors that can affect the demand for pharmaceutical products like venlafaxine. More specifically, he is expected to testify that the commercial success of Effexor XR® is largely the result of Wyeth's marketing and promotional activities, along with the well-known and inherent benefits of the active ingredient, rather than Wyeth's extended-release formulation.

Dr. Stephen R. Shuchter

University of California, San Diego
School of Medicine
2445 5th Avenue, Suite 402
San Diego, California 92101

Dr. Shuchter is a psychiatrist who is an Emeritus Professor of Clinical Psychiatry at the University of California, San Diego. He received his medical degree in 1969 from the University of Chicago. After an internship at Chicago's Michael Reese Hospital in 1969-70, he received training in general adult psychiatry at Yale University from 1970-73. He then spent two years in the U.S. Army Medical Corps, working as a psychiatrist with active-duty military, their families, and retirees at Madigan Army Medical Center. In 1975, he joined the full-time psychiatry faculty of UCSD, where he worked as a full-time professor until taking emeritus status in 2006. For almost 30 years, he was the Director/Medical Director of UCSD's outpatient clinical psychiatry service, which was the major outpatient training site for all residents, in psychiatry as well as family medicine and neurology, in addition to medical students, psychology doctoral and post-doctoral trainees, social-work trainees, and marriage and family counselors. He has researched issues related to and conducted studies regarding spousal bereavement, trauma, and the treatment of depression, and has authored or co-authored two books, several

book chapters, and numerous research papers and clinical articles. He has supervised the clinical work of over 300 residents who have spent at least a year at the UCSD clinic. His book, *Biologically Informed Psychotherapy of Depression,* was cited by the *Journal of Affective Disorders* as one of the 25 most important clinical books of the 1990s.

Dr. Shuchter is expected to testify regarding the historical use of antidepressants, up to and including Wyeth's Effexor® and Effexor XR® products, the psychopharmacologic treatment of depression and anxiety generally, and his clinical experience in prescribing Effexor® and Effexor® XR in treating depression and anxiety specifically.

Dr. Bertram Spilker

Bert Spilker & Associates, LLC
8004 Overhill Road
Bethesda, Maryland 20814-1145

Dr. Spilker is a pharmacologist and medical doctor with expertise in the formulation of pharmaceutical products, the evaluation of the results of clinical studies, and interactions between pharmaceutical companies and the U.S. Food & Drug Administration. He received his Ph.D. in pharmacology from the State University of New York in 1967, and received his medical degree from the University of Miami in 1977. After receiving his Ph.D., he worked for several pharmaceutical companies, including Pfizer, Philips-Duphar, and Sterling-Winthrop. After receiving his medical degree, he practiced medicine in Reston, Virginia and at the University of North Carolina in Chapel Hill. Between 1978 and 1993, he worked for Burroughs Wellcome Co. as a Senior Clinical Research Scientist and then as Director of Project Coordination, designing clinical trials for pharmaceutical products and analyzing their results and preparing submissions to FDA, among other duties.

In 1993, he left Burroughs Wellcome to become Corporate Vice President of Chronimed, Inc. At Chronimed, he was responsible for starting up and managing Orphan Medical, a pharmaceutical company that was initially a division of Chronimed. In 1994, Chronimed spun off Orphan Medical into a separate company, which Dr. Spilker served as President. Between

1994 and 1997, Dr. Spilker successfully built Orphan Medical into a viable company, designing its pharmaceutical portfolio, developing and implementing regulatory strategies, building the company infrastructure, and managing the development of the company's products. By the time he left in 1997, Orphan Medical was a public company listed on the NASDAQ exchange.

Then, between 1998 and 2002, Dr. Spilker served as Senior Vice President for Scientific and Regulatory Affairs for the Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade association engaged in lobbying, policy development, and advice to the pharmaceutical industry. Since 2002, he has been the principal of Bert Spilker & Associates, which consults with pharmaceutical industry groups on scientific and regulatory issues. Since 1980, he has also served as an Adjunct Professor of Medicine at the University of North Carolina School of Medicine and a Clinical Professor of Pharmacy at the University of North Carolina School of Pharmacy. Since 1993, he has served as a Clinical Professor of Pharmacy Practice at the University of Minnesota School of Pharmacy. He has authored eight books and co-authored four others, and published well over 100 additional book chapters and articles.

Dr. Spilker is expected to testify regarding Wyeth's clinical trials of its extended-release venlafaxine formulation, Wyeth's statistical methodologies in analyzing data from those studies, the clinical significance of the findings from those studies, and Wyeth's use of those findings in its submissions to the FDA. Dr. Spilker is further expected to testify regarding the state of the art in the field of extended-release formulations of pharmaceutical products at the time Wyeth began developing Effexor® XR. Dr. Spilker is further expected to provide testimony regarding how to determine whether a difference between two formulations of a drug are scientifically and clinically meaningful and the relative value of anecdotal evidence in evaluating that difference. Dr. Spilker is further expected to provide general testimony regarding FDA practice and procedures.

Dr. William E. Wecker

William E. Wecker & Associates, Inc.
505 San Marin Drive
Novato, California 94545

Dr. Wecker is a statistician and applied mathematician. He received a Ph.D. in statistics from the University of Michigan in 1972. From 1973 to 1983, he was an Assistant and then an Associate Professor in the Graduate School of Business at the University of Chicago. From 1984 to 1989, he was an Associate Professor and then Professor in the Graduate School of Management at the University of California, Davis. In 1990 he founded William E. Wecker and Associates, an applied mathematics consulting firm. From 1994 to 1998, he taught as Consulting Professor of Law at Stanford University. He is a member of the American Statistical Association, the Institute of Mathematical Statistics, and the Society for Risk Analysis. He has served as associate editor of the *Journal of the American Statistical Association* for four years and of the *Journal of Business and Economic Statistics* for eighteen years. During his career, he has published approximately 35 articles in statistical, mathematics, business, and economics journals.

Dr. Wecker is expected to testify regarding the accuracy of the claims in the specification of the Wyeth patents-in-suit regarding Effexor® XR having a statistically significant improvement in incidences of nausea over conventional Effexor, and the appropriate methods of analysis of data from Wyeth's clinical studies of Effexor® XR.